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10/663,181

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Steven Z. Wu

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11/29/2011

SQUIRE, SANDERS & DEMPSEY (US) LLP
275 BATTERY STREET, SUITE 2600
SAN FRANCISCO, CA 94111-3356

EXAMINER

WORSHAM, JESSICA N

ART UNIT

PAPER NUMBER

1615

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/663,181 | WU ET AL. | |
| | Examiner | Art Unit | |
| | JESSICA WORSHAM | 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 25,30-32 and 34-47 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 25,30-32 and 34-47 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/12/11</u> . | 6) <input type="checkbox"/> Other: ____. |

Detailed Action

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on October 12, 2011 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner. See attached copy of PTO-1449.

Status

2. The Request for Reconsideration after Non-Final filed September 12, 2011 has been acknowledged. Claims 25, 30-32, and 34-47 are currently pending. Claims 25 and 34 have been amended. Claims 44-47 are newly added but do not claim new matter. Claims 25, 30-32, and 34-47 are examined on the merits within.

Withdrawn Rejections

3. Applicant's arguments, see page 6, filed September 12, 2011, with respect to the 35 U.S.C. § 103(a) rejection of Hunter et al. in view of Hossainy et al. have been fully considered and are persuasive. The 35 U.S.C. § 103(a) rejection of claims 25, 30-32 and 34-43 has been withdrawn.

Applicant's arguments with respect to claims 25, 30-32, and 34-43 in view of Hunter et al. have been considered but are moot in view of the new ground(s) of rejection.

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New Rejections

Claim Rejections - 35 USC § 112, First Paragraph - Enablement

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 41-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a coating layer that is ‘not’ free from therapeutic substances, does not reasonably provide enablement for “a coating layer that is free from any therapeutic substances” as currently claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicant has not shown how to make and obtain a drug-free coating, particularly in view of the fact that the coating layer comprises “polymeric particles containing a therapeutic substance”. Therefore, it cannot be seen as to how the coating layer would be “free from any therapeutic substances” since Applicants are claiming *polymeric particles containing a therapeutic substance*, which are suspended within the coating layer. Hence, the claims contain contradicting language in that they require drug and yet simultaneously desire to avoid drug in the coating layer.

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Claim Rejections – 35 USC § 112, Second Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 41-43 recite “adding polymeric particles containing a therapeutic substance to a fluid form of a stent coating material, wherein the coating material comprises a polymeric material dissolved in a solvent, wherein the coating material is free from any therapeutic substance”. The claim language is indefinite because it is confusing and unclear as to how the coating layer can “be free from any therapeutic substances” when the claim explicitly recites “polymeric particles containing a therapeutic substance”. The language in the claims is contradictory claim language in that they require drug and yet simultaneously desire to avoid drug in the coating layer. How can there be a drug-free coating layer when the coating layer specifically requires drug/polymer particles in it? Clarification is requested.

Claim Rejections -35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 25, 30-32, 34, 39-44, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. (U.S. Pat. No. 6,099,562) in view of Lentz et al. (U.S. Patent Application Publication No. 2002/0133183) and further in view of Hunter et al. (U.S. Patent No. 5,886,026).

Ding et al. teach a medical device, coating and method for coating an implantable stent wherein a relatively thin layer of biostable elastomeric material in which biologically active material is dispersed as a coating is applied on the surfaces of the stent prosthesis (col. 3, line 60 – col. 4, line 7). The coating is preferably applied as a mixture, solution or suspension of polymeric material and finely divided biologically active species dispersed in an organic vehicle or a solution or partial solution of such species in a solvent or vehicle for the polymer and/or biologically active species (col. 4, lines 8-13). This reads on Applicant's medical device having a 'coating layer wherein the therapeutic substance completely encased within the polymer particles' and a 'film layer including polymeric material encasing the polymeric particles'. The term "finely divided" refers to any type or size of included material from dissolved molecules

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through suspensions, colloids and particulate mixtures. The active material is dispersed in a carrier material which may be the polymer, a solvent or both. The coating is preferably applied as a plurality of relatively thin layers sequentially applied in relatively rapid sequence and is preferably applied with the stent in a radially expanded state (col. 4, lines 14-21). Ding et al. teach that the coating may be applied by dipping or spraying using evaporative solvent materials of relatively high vapor pressure (col. 4, line 66 – col. 5, line 9).

The layered coating is referred to as the undercoat and topcoat. Typically most or all of the biologically active material is contained in the undercoat and a non-thrombogenic or biocompatible non-porous surface found in the topcoat (col. 4, lines 22-30); (col. 6, lines 6-14). The topcoat can cover either the entire undercoat or only part of the undercoat before or after implantation (col. 6, lines 50-54). In this regard, Fig. 8 demonstrates use of a topcoat containing Fluorosilicone (FSi) *only* (i.e., no drug) as compared with a Fsi topcoat containing heparin (col. 8, lines 54-57). Thus, based upon this reading the topcoat layer is free from therapeutic substance(s). In addition, column 15, lines 25-30 indicates that the layers can be used which have *no drug loadings* at all. For example, a pulsatile heparin release system may be achieved by a coating in which alternate layers containing heparin are sandwiched between unloaded layers of silicone or other materials for a portion of the coating. Thus, various combinations can be obtained with respect to controlling the release of biologically active materials. Suitable active materials disclosed include agents that inhibit hyperplasia and particularly, restenosis (col. 7, lines 30-53).

Hence, Ding et al. teach a medical device (i.e., stent) and coating method comprising application of a suspension, colloids and particulate mixtures whereby polymer/drug has been

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dispersed in an organic phase or vehicle/carrier. Ding et al. teach that such a process enables an effective method of coating an implant, such as a stent whereby a relatively thin layer of or multi-layer coating of biostable elastomeric material in which active material is dispersed can be achieved. The device comprises both an undercoat and topcoat, whereby the topcoat can be free of drug or therapeutic substances. The coating is applied onto the surfaces of the stent such as by spraying and the amount of active substance can be varied using this process.

Ding et al. do not teach that their “coating layer comprises a polymer different from the polymer from which the particles are made”.

Lentz et al. teach implantable medical devices, such as stents, provided with polymeric coatings (i.e., polyfluoro copolymers) and films to deliver pharmaceutically active material (page 8, paragraph 0084, Abstract), whereby particles of drug are fully encapsulated in the polymer (page 9, paragraph 0088) and wherein different polyfluoro copolymers may be used for different layers in the stent coating. The individual coatings may be prepared from different polyfluoro copolymers (page 8, paragraph 0084). Blends of polyfluoro copolymers may also be used. The use of different polymeric coatings provides a desired balance of coating properties, i.e., elasticity, toughness, etc. and drug delivery characteristics, such as release profile (page 8-9, paragraphs 0086-0087). Lentz et al. teach that in cases where a dispersion is applied to the stent and the smoothness of the coating film surface requires improvement, or to be ensured that all particles of the drug are fully encapsulated in the polymer or in cases where the release rate of the drug is to be slowed, a clear topcoat used to provide sustained release of the drug or another polyfluoro copolymer that further restricts the diffusion of the drug out of the coating may be applied (page 9, paragraph 0088). Lentz et al. also teach that hydrophilic polymers may be

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added to a biocompatible hydrophobic coating to modify the release profile such as polyvinyl pyrrolidone. See page 9, paragraph 0087. Additionally biopolymers can be used such as alginate biopolymers. See page 13, paragraph 0125.

Hunter et al. teach methods for treating angiogenic-dependent diseases and compositions comprising anti-angiogenic factors and polymeric carriers, stents which have been coated with such compositions and methods for utilizing these stents and compositions (see column 1, lines 15-20); (col.3, line 42 - col. 5, line 43). Methods for the preparation of drug-loaded microspheres, films and pastes are also disclosed (see Examples).

The anti-angiogenic compositions may be fashioned in the form of microspheres of any size ranging from 50 nm to 500 μ m (col. 17, lines 31-44). The compositions may also be prepared in paste or gel forms or as films (col. 17, line 45 - col. 18, line 10); (col. 37, lines 33-45). The anti-angiogenic compositions may be administered in combination with pharmaceutically or physiologically acceptable carriers, excipients or diluents (col. 37, lines 46-59).

Suitable polymeric carriers taught include poly(D,L-lactic acid), poly(glycolic acid), polycaprolactone, gelatin, starch, cellulose and polysaccharides for example and blends thereof (col. 16, lines 36-61). The anti-angiogenic compositions comprise a variety of active compounds in addition to the anti-angiogenic factors and polymeric carriers. Suitable active compounds are disclosed at column 15, lines 16-40).

The stents may be coated with the anti-angiogenic compositions or anti-angiogenic factors in a variety of ways, such as: (a) by directly affixing to the stent an anti-angiogenic composition (e.g., by either spraying the stent with a polymer/drug film or by dipping the stent

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into a polymer/drug solution), (b) by coating the stent with a substance such as a hydrogel which will absorb the anti-angiogenic composition or anti-angiogenic factor; (c) by interweaving the anti-angiogenic composition coated thread (or the polymer itself formed into a thread) into the stent structure, (d) by inserting the stent into a sleeve or mesh which is comprised of or coated with an anti-angiogenic composition or (e) constructing the stent itself with an anti-angiogenic composition (col. 22, lines 45-66).

The Examples at columns 42 onwards demonstrate various methods for the preparation of the anti-angiogenic compositions. For instance, Example 3 at column 42 demonstrates methods for the encapsulation of suramin whereby a polymer mixture is combined with the active agent (suramin) and solvent or reagent - dichloromethane (DCM). The process yields microspheres, wherein the polymer (PVA) encapsulates the active agent – suramin. Similarly, Example 4 at columns 42-43 demonstrates a procedure for the encapsulation of paclitaxel.

Example 8 at columns 45-47 outlines the manufacture of microspheres. Example 9 at columns 47-48 presents a process for the manufacture of a stent coating, wherein a sufficient quantity of polymer and DCM are added in a vial and mixed by hand in order to dissolve the polymer. An appropriate amount of paclitaxel is added to the solution and dissolved by hand shaking. The stent is coated using a horizontal spraying technique, whereby the polymer and drug are deposited on the stent.

Procedures for producing a film are discussed at columns 51-52. The films may be made by for example, casting and spraying. In the casting technique, polymer is either melted and poured into a shape or dissolved in DCM and poured into a shape. The polymer then either solidifies as it cools or solidifies as the solvent evaporates. In the spraying technique, the

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polymer is dissolved in solvent and sprayed onto glass, as the solvent evaporates the polymer solidifies on the glass. Repeated spraying enables a buildup of polymer into a film that can be peeled from the glass (col. 51, lines 55-63).

Also see Example 14 at columns 60-61, which demonstrates thermopastes made up of polymer (PCL containing MePEG) loaded with paclitaxel.

Procedures for producing a nanopaste are discussed at columns 52-53. The nanopaste is a suspension of microspheres suspended in a hydrophilic gel. The gel or paste can be smeared over tissue as a method of located drug-loaded microspheres close to the target tissue. Example 11 at columns 53-57 demonstrate controlled delivery of paclitaxel from microspheres composed of a blend of biodegradable poly(D,L-lactic acid) (PLA) polymer and non-degradable ethylene-vinyl acetate (EVA) copolymer. The microspheres are prepared by a solvent evaporation method.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate different polymeric coatings onto an implantable medical device, such as a stent, as taught by Lentz et al., within the devices of Ding et al. One would do so with a reasonable expectation of success because Lentz et al. explicitly teach implantable medical devices (i.e., stents) provided with polymeric coatings (i.e., polyfluoro copolymers) to deliver pharmaceutically active material, whereby particles of drug are fully encapsulated in the polymer and wherein different polyfluoro copolymers may be used for different layers in the stent coating. The use of different polymeric coatings provides a desired balance of coating properties, i.e., elasticity, toughness, etc. and drug delivery characteristics, such as release profile. Hunter et al. teach methods for the preparation of drug-loaded microspheres, which are

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provided as a coating onto a stent, whereby the drug (i.e., paclitaxel) is dissolved in a polymer solution containing a polymer and solvent (DCM), and wherein the solvent is evaporated to yield microspheres. Hunter et al. teach that the compositions can be in suitable forms, such as, for example, a paste, as in the form of a suspension wherein the microspheres are suspended in a hydrophilic gel, and thereafter the gel or paste can be smeared over tissue. Hunter et al. also teach compositions in the form of a film, whereby polymer is dissolved in a solvent, the solvent then evaporates and the polymer solidifies to form a film that can subsequently be peeled. The methods of Hunter et al. are useful and effective for the treatment of angiogenic-dependent diseases and thus would include restenosis, as is instantly claimed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to coat a stent taught by Hunter et al., within the devices of Ding et al. One would do so with a reasonable expectation of success because Hunter et al. explicitly teach coating methods using evaporative techniques wherein a therapeutic agent is encapsulated by polymeric particles. The expected result would be an improved drug-loaded stent for the delivery of active agents.

8. Claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. (U.S. Pat. No. 6,099,562) in view of Lentz et al. (U.S. Patent Application Publication No. 2002/0133183) and further in view of Hunter et al. (U.S. Patent No. 5,886,026) as applied to claims 25, 30-32, 34, 39-44, and 46 above and further in view of view of Iguchi et al. (U.S. Patent No. 5,756,553).

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Neither Ding et al., Lentz et al., or Hunter et al. teach a method of coating wherein the polymeric material dissolved in solvent is ethylene-vinyl alcohol copolymer, polyvinyl alcohol, or polyurethane.

Iguchi et al. teach production of a vascular stent wherein the stent was dipped in an ethylene-vinyl alcohol copolymer-cilostazol solution which was prepared by dissolving 500 mg of an ethylene-vinyl alcohol copolymer and 500 mg cilostazol in 100 ml of hexafluoro-2-propanol. The stent was air dried, dipped again, and air dried again. The resulting coated stent was dried under vacuum to remove the solvent completely. See Example 19. Iguchi et al. additionally teach that the polymer or copolymer can be polyvinyl alcohol or polyurethane. See column 1, lines 60-67, column 2, lines 1-6 and lines 62-67, and column 3, lines 1-13.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Ding et al., Lentz et al., Hunter et al., for the reasons disclosed above. In addition, it would have been obvious to combine the teachings of Iguchi et al., because Iguchi et al. teach a method of coating a stent using an ethylene-vinyl alcohol copolymer, polyvinyl alcohol, or polyurethane. The ethylene-vinyl alcohol copolymer of Iguchi et al. is different from the ethylene vinyl acetate of Hunter et al. However, the copolymers are very similar in that both contain an ethylene monomer, as well as an ethylenically unsaturated monomer. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace one copolymer of similar structure with another copolymer known in the art as a stent coating. Additionally, it would have been obvious to interchange the polymeric materials with polyvinyl alcohol or polyurethane as these are also taught as efficient polymeric materials used in coating stents.

9. Claims 45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding et al. (U.S. Pat. No. 6,099,562) in view of Lentz et al. (U.S. Patent Application Publication No. 2002/0133183) and further in view of Hunter et al. (U.S. Patent No. 5,886,026) as applied to claims 25, 30-32, 34, 39-44, and 46 above and further in view of view of Schwarz et al. (U.S. Patent Application Publication No. 2001/0022988A1).

Neither Ding et al., Lentz et al., or Hunter et al. teach polymeric particles comprising cellulose acetate phthalate or polyethylene glycol diacrylate.

Schwarz et al. teach a coating for a medical device comprising polymeric materials applied alone or in combination with therapeutic agents, and monomers that are cross-linked or polymerized. The coating materials are applied in the form of powders, solutions, dispersions, suspensions, or emulsions of one or more polymers, optionally in aqueous or organic solvents. Examples of suitable polymers include pH response polymers such as cellulose acetate phthalate or acrylate-based polymers. Other coating materials include polyvinyl pyrrolidone, polyvinyl alcohol, polyethylene glycol or acrylate-based polymer/copolymer compositions. See page 3, paragraph [0030]. The medical devices used within conjunction of the present invention include stents. See page 2, paragraph [0026].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Ding et al., Lentz et al., Hunter et al., for the reasons disclosed above. In addition Schwarz et al. teach different polymeric materials that can be used on a stent such as cellulose acetate phthalate or acrylate-based polymer/copolymer compositions. In addition the coating material can be polyethylene glycol. Polyethylene glycol diacrylate is an

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acrylate based copolymer. Therefore, if Schwarz et al. teach that either polyethylene glycol or an acrylate-based polymer/copolymer can be used in a coating material, then it would have been obvious to one of ordinary skill in the art to use polyethylene glycol diacrylate as the polymer. In addition cellulose acetate phthalate, polyvinyl pyrrolidone, and polyvinyl alcohol are known to be used in coating materials for stents, without having adverse side effects when placed in the body. Since these polymers are safe in the body, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the polymers as taught by Ding et al., Lentz et al., or Hunter et al., with a polymer taught by Schwarz et al., in order to form a stable and effective stent coating.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JESSICA WORSHAM whose telephone number is 571-270-7434. The examiner can normally be reached on Monday - Thursday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JESSICA WORSHAM/

Examiner

Art Unit 1615

/Robert A. Wax/

Supervisory Patent Examiner

Art Unit 1615